

**REMARKS**

**Status of the claims**

Claims 1-14 were pending in this application with claims 1-5, 8 and 9 having been withdrawn from active consideration by the Examiner. Thus, claims 6, 7 and 10-14 were under active consideration.

With this Response, claims 6, 7 and 10-13 have been amended, claim 15 has been newly added, and no claims have been canceled. Upon entry of this amendment, therefore, claims 6, 7 and 10-15 will be under active consideration.

Applicants respectfully request entry of the amendments and remarks made herein into the prosecution history of the present invention. Reconsideration and withdrawal of the rejections set forth in the above-identified Office Action is respectfully requested.

**Support for claim amendments**

The independent claims have been amended to recite “fabric” or “textile” comprising “a biodegradable polymeric fiber and a non-biodegradable material.” Support for this amendment, and new claim 15, may be found generally described throughout the specification as in paragraphs 0045 and 0107.

Hence, Applicants submit that no new matter has been added by this amendment. Reconsideration and allowance of all the claims is respectfully requested.

**Claim rejections under 35 U.S.C. § 102**

Claims 6, 7 and 13 stand rejected under 35 U.S.C. 102(b) as being allegedly anticipated by either MacDonald *et al.*, 1999 (*see* IDS of July 21, 2005 for complete citation, hereinafter “MacDonald”) or USP 6582955 to Martinez *et al.* (“Martinez”). The reasons for the rejections

are set forth at items 1 and 3 on page 3 of the Office Action, respectively. Applicants respectfully traverse this rejection on the following grounds.

The claims, as amended, are directed to bioreactors that comprise “vasculature” or “woven fabric forming an annular compartment” (collectively referred to herein as “bioreactor vasculature”) either of which comprise “a biodegradable polymeric fiber and a non-biodegradable material.” Neither of the cited reference disclose, let alone suggest, such material for constructing bioreactors. Hence, insofar as each and every limitation of a claimed invention must be found in a single reference to be anticipated, neither of the cited references can support a Section 102 rejection. Withdrawal of same rejection is respectfully solicited.

#### **Claim rejections under 35 U.S.C. § 102**

Claims 6, 7 and 13 stand rejected under 35 U.S.C. § 103(a) as being allegedly unpatentable over Martinez in view of USP 6840958 to Nunez *et al.* (“Nunez”) and/or USP 4816028 to Kapadia *et al.* (“Kapadia”). Claim 12 also stands rejected as allegedly obvious over Martinez in view of USP 5194157 to Ghezzi *et al.* (“Ghezzi”). Reasons for the rejections are set forth at items 3 and 4 of the outstanding Office Action, respectively. Applicants respectfully traverse these rejections.

In order to establish a *prima facie* case for obviousness, the Office must establish that each and every limitation of the claimed invention may be found in some combination of the cited references. In this respect, Applicants submit that none of the secondary references cures the deficiency of the primary reference. Namely, none of the references, alone or in combination, teach or suggest bioreactor vasculature comprising “a biodegradable polymeric fiber and a non-biodegradable material.” Rather, as the Examiner notes, Nunez and Kapadia only teach the use of woven synthetic materials, that is, *non*-biodegradable materials. Indeed, Nunez only teaches the use of “synthetic materials such as thermoplastic polymers” and Kapadia only teaches the use of “textured synthetic fiber” (*see* column 10, 1<sup>st</sup> para., and abstract, respectively). The

specifications of all three secondary references are silent with respect to biodegradable materials, let alone the advantages of using same.

As noted in paragraph 0093 of the specification, the use of biodegradable materials has distinct and unexpected advantages over non-biodegradable materials, which belies the simple substitution of one for the other. “[T]he use of vascular tubes made from woven fabrics that are composed of biodegradable materials or natural polymers results in a controlled increase in porosity and selective cell attachment focal points, respectively.” Without being held to or limited by theory, the present inventors have discovered that the use of biodegradable polymers allows for more “natural” growth and expansion of cells in a bioreactor, as degradable materials allow for cells to form structures (*e.g.*, vasculatures) similar to those found *in vivo* and not entirely along rigid and/or predetermined pathways. The biodegradable portions of the bioreactor vasculature are hypothesized to be replaced, if not entirely, by these “natural” structures. In this way, one of the most significant hurdles to long-term efficacy of bioreactors—“fouling,” caused by clogging of synthetic pores—can be, at least in part, overcome.

In sum, Applicants submit respectfully that the rejection of the pending claims under 35 U.S.C. § 103 has been traversed, and Applicants request respectfully that the rejection of same claims be withdrawn.

### **Double patenting**

Claims 6, 7 and 10-13 stand rejected for alleged non-statutory obviousness-type double patenting over claims 1-3, 23 and 29 of co-pending application no. 11/226,351 for reasons set forth on page 9. Applicants respectfully disagree with this rejection, but in any event, request that the Examiner hold this “provisional” rejection in abeyance until claims are otherwise found allowable in the present case or patented in the co-pending case. M.P.E.P. § 804 (I)(B).

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested. The Examiner

is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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